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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,413	12/20/2001	Nadia Malouf	421/29/2	3695
25297	7590	03/08/2004		
JENKINS & WILSON, PA 3100 TOWER BLVD SUITE 1400 DURHAM, NC 27707			EXAMINER MURPHY, JOSEPH F	
			ART UNIT 1646	PAPER NUMBER

DATE MAILED: 03/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/029,413	<b>Applicant(s)</b> MALOUF ET AL.	
	<b>Examiner</b> Joseph F Murphy	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 December 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-62 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I-X. Claims 1-4, drawn to a polypeptide encoded by ONE of the following: SEQ ID NO: 1, 3, 5, 6, 7, 8, 28 or 29; or the polypeptide of SEQ ID NO: 2, 4, classified in class 530, subclass 350.
- XI-XX. Claims 5-7, 22-28 drawn to an antibody which binds to ONE of the following: SEQ ID NO: 1, 3, 5, 6, 7, 8, 28 or 29; or the polypeptide of SEQ ID NO: 2, 4, classified in class 530, subclass 387.1.
- XXI-XXX. Claims 8-17, 34-37, 42 drawn to a nucleic acid molecule of ONE of the following: SEQ ID NO: 1, 3, 5, 6, 7, 8, 28 or 29; or which encodes a polypeptide of SEQ ID NO: 2, 4, vectors and host cells, classified in class 435, subclass 69.1.
- XXXI-XL. Claims 18-20, drawn to a method of producing an antibody which binds to ONE of the following: SEQ ID NO: 1, 3, 5, 6, 7, 8, 28 or 29; or the polypeptide of SEQ ID NO: 2, 4, classified in class 435, subclass 69.6.
- XLI-L. Claims 21, drawn to a method of using an antibody which binds to ONE of the following: a polypeptide encoded by SEQ ID NO: 1, 3, 5, 6, 7, 8, 28 or 29; or the polypeptide of SEQ ID NO: 2, 4, classified in class 435, subclass 7.1.
- LI-LX. Claim 29-33, drawn to a method of hybridization using a nucleic acid molecule of ONE of the following: SEQ ID NO: 1, 3, 5, 6, 7, 8, 28 or 29; or which encodes a polypeptide of SEQ ID NO: 2, 4, classified in class 435, subclass 6.

LXI-LXX. Claims 38-41, 43-52 drawn to a method of screening a compound which modulates a platelet VDCC activity wherein the polypeptide encoded by ONE of the following: SEQ ID NO: 1, 3, 5, 6, 7, 8, 28 or 29; or the polypeptide of SEQ ID NO: 2, 4, classified in class 435, subclass 7.2.

LXXI. Claims 53-54, drawn to a pharmaceutical composition comprising a modulator of the VDCC polypeptide, classified in class 530, subclass 300.

LXXII-LXXXI. Claims 55-60, drawn to a method for modulating VDCC polypeptide by transfection with a nucleic acid molecule of ONE of the following: SEQ ID NO: 1, 3, 5, 6, 7, 8, 28 or 29; or which encodes a polypeptide of SEQ ID NO: 2, 4, classified in class 514, subclass 44.

LXXXII-XCI. Claims 61-62, drawn to a transgenic animal comprising a nucleic acid molecule of ONE of the following: SEQ ID NO: 1, 3, 5, 6, 7, 8, 28 or 29; or which encodes a polypeptide of SEQ ID NO: 2, 4, classified in class 800, subclass 8.

The inventions are distinct, each from the other because of the following reasons:

Inventions I- XXX, LXXI are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function, and each has an independent use, that is distinct for each invention which cannot be exchanged. Nucleic acids, proteins, antibodies and ligands are distinct because their structures and modes of action are different, which require non-coextensive searches.

The nucleic acids of Inventions XXI-XXX are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and

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function, and each has an independent use, that is distinct for each invention which cannot be exchanged. In the instant case the nucleic acids have characteristic differences in their structure, as evidenced by the differing nucleic acid sequences.

The proteins of Inventions I-X are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function, and each has an independent use, that is distinct for each invention which cannot be exchanged. In the instant case the proteins have characteristic differences in their structure, as evidenced by the differing amino acid sequences.

The antibodies of Inventions XI-XX are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function, and each has an independent use, that is distinct for each invention which cannot be exchanged. In the instant case the antibodies have characteristic differences in their structure, as evidenced by the differing amino acid sequences of the target sequences for the antibodies.

The transgenic animals of Inventions LXXXII-XCI are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function, and each has an independent use, that is distinct for each invention which cannot be exchanged. In the instant case the transgenic animals have characteristic differences in their structure, as evidenced by the differing nucleic acid sequences of heterologous sequences.

Inventions XXXI-LXX, LXXII-XCI are independent and distinct, each from the other, because the methods are practiced with materially different starting materials, have materially different process steps, and are for materially different purposes.

Inventions XXXI-XL are independent and distinct, each from the other, because the methods are practiced with materially different starting materials, have materially different process steps, and are for materially different purposes. In the instant case, the methods of producing the antibody are different because in each Group, an antibody to a different amino acid sequence is produced.

Inventions XLI-L are independent and distinct, each from the other, because the methods are practiced with materially different starting materials, have materially different process steps, and are for materially different purposes. In the instant case the method of using the antibodies are different because for each Group a different antibody with a different specificity is used.

Inventions LI-LX are independent and distinct, each from the other, because the methods are practiced with materially different starting materials, have materially different process steps, and are for materially different purposes. In the instant case the method of hybridization is practiced with a different nucleic acid sequence.

Inventions LXI-LXX are independent and distinct, each from the other, because the methods are practiced with materially different starting materials, have materially different process steps, and are for materially different purposes. In the instant case the method of screening is carried out using a different polypeptide sequence, as evidenced by the different sequence identifiers.

Inventions LXXII-LXXXI are independent and distinct, each from the other, because the methods are practiced with materially different starting materials, have materially different process steps, and are for materially different purposes. In the instant case the method is

practiced with different starting materials since the transfection requires the use of different nucleic acid sequences as evidenced by the different sequence identifiers.

Inventions XXXI-XL and XI-XX are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the antibody can be produced synthetically.

Inventions XI-XX and XLI-L are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody can be used in a method of isolation of the protein.

Inventions XXI-XXX and LI-LX, LXXII-LXXXI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid can be used for the production of protein.

Inventions I\_X and LXI-LXX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case the polypeptide can be used in a method of producing an antibody.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.



In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

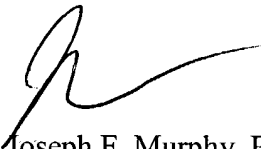
#### ***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Murphy whose telephone number is (571) 272-0877. The examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 272-0871.

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The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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Patent Examiner  
Art Unit 1646  
March 4, 2004